

Laboratory Proficiency Testing

Definition: Successful performance is defined as enrollment in an approved proficiency testing program, participation in testing events, and acceptable grades in two of three successive testing events.

Summary

The Department of Health's Medical Test Site program monitors proficiency testing performance of most medical laboratories in Washington (the exception being 173 large hospital and commercial labs that are accredited by federally-approved private testing agencies).

The state program uses proficiency testing performance as one means of assessing the accuracy and reliability of the clinical laboratory testing done on patient specimens. In 1994 the program monitored proficiency testing performance for more than 99% of the facilities for which it has responsibility. Of those, 86% had successful performance.

Time Trends

Washington's regulation of clinical laboratory testing began in September 1990. Regulated sites must participate and perform successfully in a proficiency testing program approved by the federal government. Enrollment and successful participation in proficiency testing has been monitored since 1991.

From 1991 to 1993, monitoring consisted mainly of education and assistance in getting sites properly enrolled in an approved proficiency testing program. In 1993, laboratories were

expected to be in full compliance with the testing requirements and were subject to disciplinary actions for unsuccessful performance.

In 1993, 97% of the sites were monitored; of those, 85% had successful performance. In 1994, over 99% were monitored; of those, 86% had successful performance.

A comparison of state and national trends on successful proficiency testing performance is not possible at this time. Although the federal laboratory regulations required participation in proficiency testing starting January 1994, performance was not monitored until 1995.

Year 2000 Goal

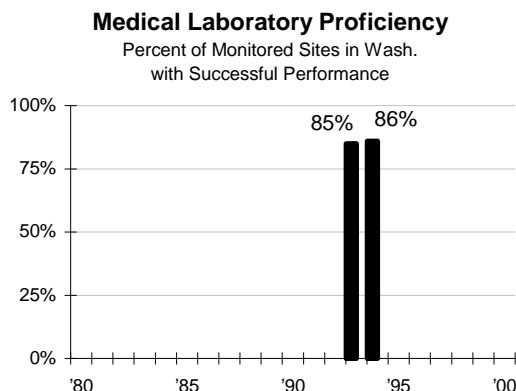
No specific year 2000 goal has been set for proficiency testing monitoring. The current target goal of 100% monitored sites will continue to be the objective.

No year 2000 goal has been determined for the percent of monitored sites with successful performance.

Types of Laboratories

The table below shows types of laboratories monitored by the Department of Health in 1994 and the number and percent with successful performance.

	Number Monitored	Number Successful	Percent Successful
Physician Office	351	298	85%
Clinic	67	57	85%
Independent	43	41	95%
Hospital	30	25	83%
HMO	25	24	96%
Com. Clinic	23	19	83%
Health Dept.	20	18	90%
Other	50	42	84%
Total	609	524	86%



The Medical Test Site program recognizes private laboratory accreditation agencies that are approved by the federal government. Of the 770 licensed sites required to participate in proficiency testing in 1994, 158 were accredited laboratories (large hospitals and commercial facilities). The accrediting agencies are responsible for monitoring these laboratories. Information on proficiency testing performance of these labs is not maintained by the state program and is not included in the statistics presented here.

Nature of the Proficiency Tests

Proficiency testing is a process designed to assess accuracy and reliability of medical laboratory testing systems. Synthetic test specimens are sent by a proficiency testing company to a laboratory for testing. The laboratory's results are graded by comparison with expected results of the synthetic material.

Laboratories are required to participate in proficiency testing for all tests for which service is offered and for which approved proficiency testing is available. Approved programs are available for chemistry, hematology, immunology, microbiology and immunohematology specialties.

Proficiency testing is considered one of the most important measures of laboratory performance since actual results are reviewed, rather than processes that merely gauge the potential for good laboratory results.

Common Reasons for Unsuccessful Performance

Some of the more common reasons for unsuccessful performance are lack of experience with the process, nonenrollment in an approved program, equipment failure, reagent problems, and older instruments or methods that have a limited peer group for comparison. Once a laboratory becomes familiar with the process, proficiency testing is an important tool for assessing problems with its test systems.

Other Measures of Laboratory Proficiency

Proficiency testing performance is one indicator used to assess the quality of testing performed in a laboratory. In addition to monitoring proficiency testing performance, laboratories are also inspected on a biennial basis. The inspection process assesses compliance with

all aspects of the medical test site regulations, including personnel, record keeping, quality assurance, quality control, and proficiency testing.

In 1993, 311 laboratories were inspected, with 54% having no deficiencies. In 1994, 397 laboratories were inspected with 38% having no deficiencies. The decrease in numbers of laboratories with no deficiencies in 1994 was due to rule changes made in September 1993 to bring the State Medical Test Site rule into compliance with Federal regulation. Because of these changes, many of the laboratories were inspected for the first time in 1994.

A study done by the department in January 1994 compared findings from initial inspections in 1991 with findings of subsequent inspections two years later.¹ Of 101 laboratories reviewed, 65% showed a decrease in the number of deficiencies cited on their second inspection.

Risk and Protective Factors

The proficiency testing performance of laboratories seems to correlate with oversight by trained laboratory personnel. The highest percentage of successful performance in 1994 was in independent laboratories (95%) and HMOs (96%). These laboratories have thorough training programs for their personnel and have experienced laboratory technologists who provide oversight of the laboratory testing.

The sites that tend to show poor performance are often newly regulated sites that are unfamiliar with the requirements and do not have oversight by a laboratory professional. They may neglect to enroll in an approved program, have trouble filling out the paperwork properly, or not test the specimens within the specified time period. Turnover in personnel also seems to contribute to failure in sites that are not supervised by a laboratory professional.

Intervention Points, Strategies and Effectiveness

Ongoing monitoring allows timely detection of unsuccessful performance and the opportunity to intervene and help the laboratory correct problems.

When unsuccessful performance is noted, the laboratory, regardless of type, is given the following options: 1) undertake appropriate training for the testing personnel involved; 2) employ technical assistance necessary to correct

the problem; 3) perform special studies such as testing additional patient specimens (split sample study) from a reference laboratory; 4) obtain and analyze additional specimens from a proficiency testing program; or 5) discontinue the test.

Department of Health staff do a thorough review of the unsatisfactory results to offer consultation and guidance in the type of corrective action needed.

If a laboratory continues to show unsuccessful performance after completing their corrective action plan, they are required to discontinue the test. If the laboratory refuses to comply with the request to discontinue a test, disciplinary action such as revocation, suspension, or placing conditions on a license would be taken. To date, there have been no disciplinary actions taken because of unsuccessful proficiency testing performance, as laboratories have complied with the request to discontinue patient testing until they can demonstrate successful performance on two proficiency testing events.

Data Sources

State data, collected and prepared by Washington Department of Health, Office of Laboratory Quality Assurance

For More Information

Washington Department of Health, Office of Laboratory Quality Assurance, (206)361-2802

Endnotes:

¹ Assessment of the Quality of Laboratory Testing. January 1994. Washington State Department of Health, Office of Laboratory Quality Assurance.